

**Appl. No.** : 09/980,682  
**Filed** : August 15, 2002

### **REMARKS**

In the Office Action, the Examiner indicated that Claims 86-92 are allowed.

The Examiner objected to the drawings for the informalities of including the captions "SUBSTITUTE SHEET (RULE 26)" and "PCT/AU00/00355". The Applicant hereby enclosed substitute drawings sheets with the elimination of the captions of the original drawings.

The Examiner also objected to the claims and the numbering thereof as not being in accordance with the requirements of 37 CFR 1.126 and particularly objected to Claims 82-84 under 37 CFR 1.75(c) as being of improper dependent form as depending upon a nonexistent Claim 63. The Applicant respectfully notes that Claims 1-96 correspond to the claims of the international application PCT/AU00/00355 as amended before the International Authority on August 9, 2001, and as further amended by the Applicant's preliminary amendment of October 23, 2001. The Applicant's understanding of the procedures for preparation and filing of amendments at that time were to indicate clean copies of the amended claims as well as a copy of the amended claims with markings to indicate changes made thereto. The claims indicated as missing from the subject application by the Examiner, i.e. Claims 47, 59, 63, and 85 were not amended with the Applicant's preliminary amendment of October 23, 2001 and are thus understood to be prosecuted on the basis of their standing of the Applicant's amendment before the International Authority of August 9, 2001. The Applicant further notes that the Examiner's restriction requirement of December 19, 2003 considered Claims 1-96 including Claims 47, 59, 63, and 85 and that the Applicant's response to the restriction requirement electing Claim Group I, i.e. Claims 1-69 and 73-92 were also made with Claims 47, 59, 63, 85 being considered. Thus, the Applicant believes that the numbering of claims is in accordance with 37 CFR 1.126 and that the objection made by the Examiner to Claims 82-84 under 37 CFR 1.75(c) is improper. The Applicant notes that a complete listing of claims with their current status is included with this paper.

The Examiner also rejected Claims 79 and 81 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the Examiner notes that Claim 79 refers to a "HQ characteristic" and notes that the acronym HQ is

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undefined. The Applicant thanks the Examiner for noting this discrepancy and hereby amends Claim 79 to recite a “pressure versus flow rate” characteristic which the Applicant believes clearly defines what the Applicant regards as the invention and amends Claim 81 for proper dependence upon the antecedent elements recited in Claim 79 as currently amended.

The Examiner also rejected Claims 1-8, 11-16, 18-22, and 25 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 8-11, 13-18, and 19-27 respectfully of U.S. Patent 6,250,880. Applicant hereby submits concurrently herewith a Terminal Disclaimer in accordance with 37 CFR 1.321(c) and 37 CFR 1.130(b) to overcome the non-statutory double patenting rejection with respect to the Applicants’ U.S. Patent 6,250,880.

The Examiner also rejected Claims 1-27 under 35 U.S.C. § 102(d) as being barred by Applicants’ published PCT Application WO 99/12587. The Applicants respectfully note that Claim 1 is hereby amended to claim “A rotary blood pump for use in a heart assist device, the pump comprising; an impeller comprising an even number of blades and **generally circumferentially extending struts interconnecting the blades at an outer periphery of the impeller...**” (Claim 1 as currently amended). The Applicant respectfully notes that these aspects of Claim 1 as currently amended are not disclosed in the Applicant’s published PCT Application WO 99/12587. Thus, the Applicant believes that Claim 1 and Claims 2-27 depending therefrom are novel and patentable under the requirements of 35 U.S.C. § 102(d).

The Examiner also rejected Claims 28, 73, 74, 77, and 78 under 35 U.S.C. § 102(b) as being anticipated by Hubbard et al US 4,781,525. The Applicant has carefully reviewed the Hubbard et al ‘525 reference and notes the following differences between the disclosure of Hubbard et al ‘525 and the Applicant’s claimed invention. In particular regarding Claim 28 as currently amended, the Applicant claims “An estimation and control system for a pump, the pump of the type having an impeller located within a pump cavity in a pump housing ... whereby the impeller, in use, substantially resists five degrees of freedom of movement with respect to the pump housing solely via hydrodynamic forces...”. The Applicant notes that Hubbard et al ‘525 discloses a “Centrifugal blood pump 16 includes housing 18, inlet 20, outlet 22, impeller 24, and drive shaft 26. Motor 28 provides rotary drive to drive shaft 26 and thus to impeller 24, through coupling 30. In one embodiment, coupling 30 is a

magnetic type coupling, and in other embodiments is a quick connect/disconnect shaft coupling. As motor shaft 32 of motor 28 is rotated, coupling 30 imparts the rotary drive to pump drive shaft 26. This causes impeller 24 to rotate within housing 18.” (cf. Column 2, Lines 26-34). Thus, Hubbard et al `525 clearly teaches that the impeller 24 is driven and supported within the housing 18 by the drive shaft 26 and not via hydrodynamic forces as in the Applicant’s claimed invention of Claim 28 as currently amended.

Regarding Claim 73 and Claims 74, 77, and 78 depending therefrom the Applicant respectfully notes that the claimed invention includes “An estimation and control system for a pump ... the pump maintained at or near a predetermined operating point by a controller acting on the impeller drive ... wherein instantaneous pump speed and electrical input power are allowed to be modulated by a heart, in use, by appropriate selection of a controlled time constant...”. The Applicant respectfully notes that Hubbard et al `525 teaches an apparatus and method for calibrating and setting the drive point of the centrifugal pump system 10 and includes exemplary tables of control algorithm parameters comparing measured and calculated flow and input torque (input power) at a plurality of discrete revolution rates of the pump 10. The teachings of Hubbard et al `525 include the ability to relatively accurately calculate the flow output characteristics of the pump once the system has been calibrated to the particular viscosity of the fluid being pumped without requiring a separate flow measurement device to be introduced into the fluid outlet of the pump. However, the Applicant respectfully notes that Hubbard et al `525 does not disclose modulating the instantaneous pump set point, e.g. speed and input power to be modulated, such as by the varying hemodynamic characteristics of a beating heart via appropriate selection of a controlled time constant so as to avoid under or over pumping. As described in the subject application, avoidance of over and under pumping is of particular value in an in vivo application where the patient’s metabolic need would be expected to vary considerably throughout the course of the day and their daily activities which the rate responsive aspects of the Applicant’s claimed invention provides. The Hubbard et al `525 device is disclosed as “...typically used in providing life support to a patient (not shown) during open surgery or heart assist.” (cf. Column 2, Lines 19-22) and is thus adapted for a clinical setting where the patient’s metabolic need would be expected to remain substantially constant.

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Thus, Hubbard does not disclose "An estimation control system for a pump ... wherein instantaneous pump speed and electrical input power are allowed to be modulated by a heart, in use, by appropriate selection of a controlled time constant...".

Thus Claims 28 and 73 as currently amended are believed novel and patentable under the requirements of 35 U.S.C. § 102(b) over the teachings of Hubbard et al '525. As the claims depending therefrom, i.e. Claims 29-32, 34-69, and 74-85, respectively, properly depend from and further define the Applicant's claimed invention, the Applicant believes that these claims are allowable as well.

Appl. No. : 09/980,682  
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### SUMMARY

From the foregoing, the Applicant believes that the application as currently amended does particularly point out and distinctly claim the subject matter which the Applicant regards as the invention as required by 35 U.S.C. § 112, second paragraph. The Applicant further believes that the claimed invention of the subject application is not subject to an obviousness-type double patenting rejection over the Applicant's prior U.S. Patents 6,227,797, 6,250,880, nor 6,609,883 and is not barred under 35 U.S.C. § 102 by Applicant's prior patents nor by the published PCT Application WO 99/12587. The Applicant thus believes that the application is in a condition ready for allowance and respectfully requests prompt issuance of a Notice of Allowability. The Applicant believes that this paper is fully responsive to the objections and rejections made by the Examiner to the drawings and pending claims of the application. However, should there remain any further impediment to the allowance of this application that might be resolved by telephone conference, the Examiner is respectfully requested to contact the Applicant's undersigned representative at the below-indicated telephone number

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

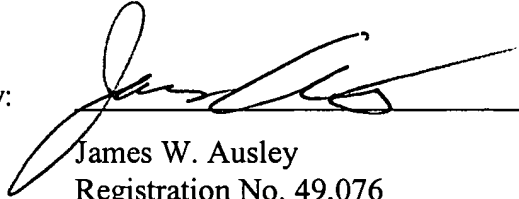
Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: \_\_\_\_\_

8/3/04

By: \_\_\_\_\_

  
James W. Ausley  
Registration No. 49,076  
Agent of Record  
Customer No. 20,995  
(909) 781-9231